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REMARKS

This response is intended as a full and complete response to the non-final Office Action mailed September 22, 2003. In the Office Action, the Examiner notes that claims 1-41 are pending of which claims 1-41 are rejected. By this amendment, the applicants have amended claims 1, 11, 21, 23, 25, 28 and 38 and canceled claims 26 and 30-34. Claims 2-10, 12-20, 22, 24, 27, 29, 35-37, and 39-41 continue unamended.

In view of both the amendments presented above and the following discussion, the applicants submit that none of the claims now pending in the application are indefinite, anticipated, or obvious under the respective provisions of 35 U.S.C. §112, §102, and §103. Thus, the applicants believe that all of these claims are now in allowable form.

It is to be understood that the applicants, by amending the claims, do not acquiesce to the Examiner's characterizations of the art of record or to applicants' subject matter recited in the pending claims. Further, applicants are not acquiescing to the Examiner's statements as to the applicability of the art of record to the pending claims by filing the instant responsive amendments.

OBJECTIONS

The Examiner has objected to claim 38 "because of the following informalities: in line 3, "interface e..." should read --interface--." By this amendment, applicants have amended claim 38, line 3 as suggested by the Examiner. Therefore, applicants respectfully request that the rejection be withdrawn.

THE REJECTIONS

1. **35 U.S.C. §102**

The Examiner has rejected claims 1, 10, 21, 23, 30-34 under 35 U.S.C. 102(b) as being anticipated by Behbehani et al. (U.S. Patent No. 5,953,713, hereinafter "Behbehani"). In view of the cancellation of claims 30-34, it is respectfully submitted that the Examiner's rejection of these claims is moot. With respect to claims 1, 10, 21 and 23, the applicants respectfully traverse.

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The Behbehani reference discloses taking samples of respiration-related variables at 512 Hz (i.e., more than twice the frequency associated with snoring) to produce a time domain sample set that is transformed, using a fast Fourier transform (FFT) to produce frequency data, i.e., spectral data such as shown in FIG. 2 of Behbehani. This frequency data is processed by an artificial neural network (ANN) which identifies energy levels within spectral regions associated with pharyngeal wall vibrations (i.e., snoring). In this manner, a determination is made by the ANN as to whether a monitored subject is experiencing snoring.

"Anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim" (Lindenmann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984) (citing Connell v. Sears Roebuck & Company, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)) (emphasis added). Behbehani fails to each or disclose each and every element of the claimed invention, as arranged in the claim.

Applicants' independent claim 1, as amended, recites:

"A method for the detection and treatment of disordered breathing during sleep employing an artificial neural network (ANN) in which data related to breathing gas flow are analyzed, comprising:
placing a mask with a tube over a patient's airway, the mask being in communication with a source of a pressurized breathing gas controlled by a continuous positive airway pressure (CPAP) system, thereby establishing a respiratory circuit;
periodically sampling the gas flow in the circuit;
performing a linear predictive coding (LPC) multiple parameter analysis for each sample to provide thereby respective A-parameters;
converting said A-parameters into cepstrum parameters;
processing said cepstrum parameters using an ANN trained to recognize breathing patterns characteristic of sleep disordered breathing; and
controlling a breathing gas pressure in response to an output of said ANN."

In contrast to the above-quoted claim language, there is absolutely no teaching or suggestion within the Behbehani reference to perform the claimed "linear predictive coding analysis" and subsequent conversion "into cepstrum parameters" for "processing ... using an ANN...." Moreover, it is noted that the claimed invention performs such analysis and processing on each periodically retrieved sample.

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In contrast to the frequency domain processing utilized by the Behbehani arrangement, the claimed invention utilizes a linear predictive coding (LPC)-cepstrum 4-parameter analysis. Specifically, the LPC and cepstrum processing of the subject invention comprises a time domain process utilizing cepstrum coefficients. That is, the ANN of the claimed invention uses time domain data that <u>models frequency domain information</u> indicative of a breathing disorder. By contrast, the Behbehani patent <u>derives the actual frequency information</u> used to make the breathing disorder determination. In this manner, the claimed invention advantageously avoids the processing of frequency data, unlike the cited reference. The subject invention periodically samples breathing gas <u>flow</u>, rather than pressure as in Behbehani. For <u>each sample</u>, a value for at least one parameter distinctive of a breathing pattern is calculated such that a feature vector is formed. An artificial neural network (ANN) processes the feature vector(s) to identify anomalies which have been determined to reflect the presence of disordered breathing. Thus, the subject invention utilizes LPC-cepstrum data, not frequency data. Moreover, the LPC-cepstrum data or parameters processed by the ANN are generated by processing <u>each</u> gas <u>flow</u> sample periodically retrieved from a respiratory circuit.

Therefore, Behbehani fails to teach <u>each and every</u> element as arranged in claim 1. As such, the applicants submit that claim 1 as amended is not anticipated and fully satisfies the requirements of 35 U.S.C. §102 and is patentable thereunder. Furthermore, claims 2-20 depend, either directly or indirectly, from independent claim 1 and recite additional limitations thereof. As such, and for at least the reasons as discussed above, the applicants submit that these dependent claims also fully satisfy the requirements of 35 U.S.C. §102 and are patentable thereunder. It is also noted that claims 21 and 23 have been amended to include the relevant limitation discussed above with respect to claim 1. As such, and for at least the reasons discussed above with respect to claim 1, the applicants submit that independent claims 21 and 23, and their respective dependent claims 22 and 24 also fully satisfy the requirements of 35 U.S.C. §102 and are patentable thereunder.

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2.   **35 U.S.C. §103**

    a.   **Claims 2, 3, 5-8, 12-16**

The Examiner has rejected claims 2, 3, 5-8, 12-16 as being obvious under 35 U.S.C. §103 over Behbehani. The applicants respectfully traverse the rejection.

The test under 35 U.S.C. §103 is not whether an improvement or a use set forth in a patent would have been obvious or non-obvious; rather the test is whether the claimed invention, considered as a whole, would have been obvious. Jones v. Hardy, 110 USPQ 1021, 1024 (Fed. Cir. 1984) (emphasis added). Thus, it is impermissible to focus either on the "gist" or "core" of the invention, Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 230 USPQ 416, 420 (Fed. Cir. 1986) (emphasis added). Behbehani fails to teach the applicants' invention as a whole,

Claims 2, 3, 5-8 and 12-16 are dependent from claim 1, either directly or indirectly, and patentable for at least the reasons discussed above with respect to claim 1.

Further with respect to claims 2 and 3, and as noted by the Examiner, "Behbehani et al. do not specify the particular rate at which data is fed into the neural network ...." However, the Examiner contends that this deficiency in the teachings of Behbehani with respect to the invention of claims 2 and 3 is satisfied by the contention that "one of ordinary skill would recognize that the rate at which data is actually fed into the neural network may be varied to correspond to a rate which is consistent with a number of patient breaths or partial breaths." This is an inappropriate assumption to make. For example, the Behbehani arrangement does not disclose or suggest any mechanism by which a number of patient breaths or partial breaths is counted, much less some mechanism by which such a count is used to adapt a rate of data input to a neural network. Moreover, it is noted that the high sampling rate of Behbehani obviates the need to perform such sample rate adaptation, since the high sample rate (with respect to patient breath count) provides sufficient data to perform the snore detection processes described in the Behbehani reference. A low data rate is not appropriate to the Behbehani arrangement, nor is it disclosed within the Behbehani reference. As such, it is inappropriate for the Examiner to reject claims 2 or 3 on these grounds. As such, it is respectfully submitted that claims 2 and 3 are patentable.

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Of particular importance is the frequency domain at which the Behbehani reference operates. Specifically, a normal flow measurement for a patient breathing comprises a relatively gentle oscillation having a normalized magnitude of 1 and a frequency of, Illustratively, 0.3 Hz. Where snoring exists, the spectral region associated with the snoring is typically around 140-150 Hz. Thus, by sampling at 500 Hz, the Behbehani reference is able to identify spectral energy reasons associated with snoring. By contrast, the subject invention operates at a much slower sampling frequency, e.g. 20 Hz. This is because the subject invention is not directed towards identifying or otherwise analyzing snoring. Rather, the subject invention is directed towards determining whether appropriate flow exists, thereby providing warning of an obstruction or other inhibition to proper air flow within a patient.

Further with respect to claims 5-8, the Examiner takes official notice that "neural networks which are intended for use as controllers of medical devices are typically 'trained' using as large a number of patients as possible and under the conditions in which the patients are intended to be treated (e.g., sleeping) in an effort to provide as large a data base of information as possible." The applicants respectfully request that the Examiner submit a reference supporting this official notice.

Further with respect to claim 14, the Examiner attempts to bridge the substantial gap between the Behbehani teachings and the invention of claim 14 by contending that "training the neural network would typically include data which define apnea conditions as well as normal conditions. The data which define an apnea condition would typically include data which covers all portions of the event from its initial stages through any recovery." The Examiner proffers no support whatsoever for this contention. The Behbehani reference is directed to snoring. The training of the neural network as characterized by the Examiner differs from the training of the neural network as described in the Behbehani reference itself.

Further with respect to claim 14 (among others), the "apneic condition" discussed by the Examiner is not the apneic condition addressed by Behbehani. Specifically, Behbehani is solely interested in the spectral region associated with snoring. There is no "event" having an initial stage through a recovery stage that is of interest in the Behbehani arrangement other than a snoring event, which snoring event occurs at a spectral region very different than the region of the claimed invention.

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As noted in column 3 of Behbehani, lines 56-67:

> "A fast Fourier transform (FFT) is performed on the pressure data measured by the transducer to obtain the frequency spectra depicted in Figure 2. As can be seen, there is a marked peak in spectrum 19 corresponding to sleep disorder breathing in the range between 100 and 150 Hz. This is indicative of pharyngeal wall vibration, which is the precursor to most forms of sleep disorder breathing. This peak is not present in spectrum 21 corresponding to normal breathing. Thus, there is a clear distinction between the spectrum corresponding to pharyngeal wall vibration, or sleep disorder breathing, and that corresponding to normal breathing. This distinction is employed to detect sleep disorder breathing in the method and apparatus according to the present invention."

Thus, it is clearly stated within the Behbehani reference that the Behbehani reference is solely directed to sleep disorder breathing in the range between 100 and 150 Hz, which sleep disorder breathing comprises snoring. Moreover, it is clearly noted in the above-quoted portion that pressure data measured by a transducer is used to obtain the sample data processed in the Behbehani arrangement. By contrast, the subject invention utilizes flow data and, importantly, the subject invention utilizes flow data within a spectral region adapted to identify flow limitation or obstruction problems, not snoring problems.

Further with respect to claims 15 and 16, the Behbehani arrangement does modify the pressure of air supplied to the patient in response to the detection of a snoring condition. However, this is not the same as modifying the flow of air in response to a detected flow limitation condition. As such, the logic presented by the Examiner with respect to claims 15 and 16 does not apply, and the claims are, it is respectfully submitted, patentable.

As such, the applicants submit that claims 2, 3, 5-8, 12-16 are not obvious and fully satisfy the requirements of 35 U.S.C. §103 and are patentable thereunder. Therefore, the applicants respectfully request that the rejection be withdrawn.

b.   Claims 4, 11, 17, 18, 22, 24-29, 35-41

The Examiner has rejected claims 4, 11, 17, 18, 22, 24-29, 35-41 under 35 U.S.C. §103(a) as being unpatentable over Behbehani in view of Lin et al. (U.S. Patent No. 5,666,466 (hereinafter "Lin").

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The Lin arrangement comprises a method and apparatus for speaker recognition using selected spectral information. That is, Lin is directed to identifying a speaker based on selected spectral information from the speaker's voice. It is respectfully noted that the spectral region appropriate to voice and/or tonal inflections is entirely different than that spectral region addressed by the claimed invention.

The Examiner contends that "it would have been obvious to modify the neural network of Behbehani et al. to employ any well known type of neural network including Kohonen neural network as taught by Lin et al. because it would have constituted the mere substitution of one type of neural network for another." The applicants respectfully disagree. It is noted that the applicants are not claiming a neural network by itself; rather, the applicants claim the use of a neural network operating in a particular manner, upon a particular set of data, which data set is generated according to a particular technique. It is inappropriate to contend that the teachings of Lin are reasonably imported into the Behbehani reference such that the significant differences between the Behbehani arrangement and the claimed invention are somehow bridged.

The applicants respectfully submit that the combination of the Lin arrangement and Behbehani arrangement is inappropriate and inoperable. The two arrangements have entirely different functions, produce entirely different results and solve entirely different problems. There is also no motivation to combine such references.

Column 4, lines 13-49 of Behbehani describe the "preferred artificial neural network according to the present invention." This preferred ANN has certain characteristics that are described in some detail, including the fact that the ANN is of the "15-2-2-1 feed-forward topology having full conductivity and 88 weight." It is further noted in this portion of Behbehani that:

> "It has been found that this type of neural network topology strikes a satisfactory balance between accuracy in detecting sleep disorder breathing and deficient use of computational power. A larger or more complex neural network could be selected to enhance accuracy, but the computational power required would be excessive."

As described in Lin, referring to column 3, an appropriate processing means comprises a Sun Sparc workstation. Since the Sparc station implementation of the Lin arrangement utilizes, e.g., 40 vectors (column 4, lines 32-40), it is respectfully submitted that the Behbehani arrangement teaches away from utilizing such a complex,

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computationally powerful system. Specifically, the purpose of Behbehani is to provide a reasonably priced means of detecting snoring and altering and responsively adjusting gas pressure for a patient. The cost and complexity of using apparatus such as described in Lin would defeat the purpose of the Behbehani arrangement.

With respect to claims 4, 11, 17-18, 22, 24-29 and 35-41, the applicants strongly object to the combination made by the Examiner of the Behbehani arrangement and Lin arrangement. The Examiner is inappropriately using hindsight to pick and choose those elements within the prior art that, when cobbled together to form some sort of arrangement, appear on their face to disclose or suggest the claimed invention. The applicants respectfully note that such hindsight is impermissible and that the teachings of Behbehani, the problem solved by Behbehani and the problem solved by Lin are entirely different and their respective arrangements cannot simply be dissected in part and combined to somehow arrive at the claimed invention.

Applicants respectfully submit that even if the combination of Behbehani and Lin were somehow made, the resulting combination fails to teach the applicants' invention as a whole. It is also noted that such a combination would fail to embrace the properties of applicants' invention and the problem it solves.

As such, the applicants submit that claims 4, 11, 17, 18, 22, 24-29, 35-41 are not obvious and fully satisfy the requirements of 35 U.S.C. §103 and are patentable thereunder. Therefore, the applicants respectfully request that the rejection be withdrawn.

c.   **Claim 9**

The Examiner has rejected claim 9 under 35 U.S.C. §103(a) as being unpatentable over Behbehani in view of Pardey et al. (U.S. Patent No. 5,999,846 (hereinafter "Pardey").

Claim 9 is patentable for at least the reasons discussed above with respect to claim 1, from which it depends.

The Pardey reference teaches a physiological monitoring system in which an electrical signal related to the sleep or wakefulness stage type experienced by a subject is monitored and used for, among other processes, training and testing a neural network for use in a physiological monitor.

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Applicants respectfully submit that the combination of Behbehani and Pardey fails to teach the applicants' invention <u>as a whole</u>. Specifically, Pardey fails to bridge the substantial gap as between Behbehani and applicants' invention. In particular, Pardey merely discloses the training of a neural network using electrical impulses derived from a subject. The invention comprises more than this, since the invention of claim 9 depends from claim 1 and includes those additional limitations.

Even if the two references could somehow be operably combined, the combination would merely disclose a system requiring multiple monitoring inputs (i.e., respiratory pressure and electrical impulses) that enables the training of an overly complex neural network. The complexity of such neural network is contrary to the purposes of the Behbehani neural network as discussed above with respect to the Lin reference. Therefore, the combined references <u>teach away</u> from the applicants' invention.

As such, the applicants submit that 9 is not obvious and fully satisfies the requirements of 35 U.S.C. §103 and is patentable thereunder. Therefore, the applicants respectfully request that the rejection be withdrawn.

3.   <u>35 U.S.C. §112</u>

The Examiner has rejected claims 11, 19 and 20 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Regarding claim 11, the Examiner asserts that "the phrase 'map like' renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by 'or the like'), thereby rendering the scope of the claims unascertainable." The applicants' counsel has reviewed claim 11 and does not find the phrase "map like" present in the claim. However, claim 11 has been amended to replace the term "map type" with the term "map."

Regarding claims 19-20, the Examiner asserts that "In each of claims 19 and 20 '... the prediction error...' and '... said prediction error...' lack antecedent basis; moreover, the scope of the terminology 'prediction error' is not clear from the claim language. That is, the process which applicant employs to generate a 'prediction error' is not apparent from the claim language."

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In response, claim 19 has been amended to more clearly define the antecedent basis. Claim 20 is proper in view of the amendment to claim 19.

CONCLUSION

The applicants believe all the claims are presently in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issue are earnestly solicited.

If, however, the Examiner believes that there are any unresolved issues requiring the issuance of an adverse final action in any of the claims now pending in the application, it is requested that the Examiner telephone Eamon J. Wall, Esq. at (732) 530-9404 so that appropriate arrangements can be made for resolving such issues as expeditiously as possible.

Respectfully submitted,

12/22/03

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